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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/522,955      | 11/14/2005  | Richard Martyn Angell | P33089              | 4648             |

20462 7590 11/19/2008  
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| EXAMINER |
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CHU, YONG LIANG

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

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|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

11/19/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/522,955 | <b>Applicant(s)</b><br>ANGELL ET AL. |  |
|                              | <b>Examiner</b><br>YONG CHU          | <b>Art Unit</b><br>1626              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-11 is/are rejected.
- 7) ☒ Claim(s) 6 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/27/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 13-26 are new by the amendment. Claims 1-24 are pending in this application. Claims 13-26 are provisionally withdrawn from further consideration as non-elected subject matter, but are subject to rejoin if the currently examined claims are found allowable. Therefore, claims 1-12 are under examination on the merits.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement, filed 08/27/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

### ***Priority***

This application is a 371 of PCT/GB03/03316 filed on 07/30/2003, and claims foreign priority of U.K. Patent Application No. 0217757.4 filed on 07/31/2002.

### ***Response to Arguments***

#### **Argument over rejection of claims under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

Applicant's arguments over rejection of claims 8 and 9 for non enabling for treating "any condition or disease state mediated by p38 kinase activity in a patient" on the ground that signaling pathway of p38 kinase had been extensively studies, and the previously provided references by Applicants on the linkage of p38 cascade to a number of acute and chronic inflammatory diseases, therefore, use of p38 inhibitors for the treatment of inflammatory diseases is known in the art has been fully considered, but is found not persuasive. The rejection is based on claiming a method of using the

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said compounds to treat **any** condition or disease state mediated by p38 kinase activity, not just "inflammatory diseases". Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807. See also MPEP2111.01(II). Therefore, the rejection is maintained.

To overcome the rejection, Applicants may further limit the diseases with support in the specification.

**Argument over rejection of claims under 35 U.S.C. §103(a)**

Applicant's arguments over rejection of claims 1-3, 5, and 7-11 have been fully considered, but are found not persuasive. Applicant's argument that the Application with publication number WO2003/097610 is not effective unless it has entered the US and published therein is not persuasive. The cited '610 publication designated to U.S. and is not required entering U.S. and published therein to be qualified as a 102(e) reference, because it is not an ODP rejection. The effective filing date of the '610 publication is 05/17/2002, which beats the priority date of the instant application (i.e. 07/31/2002). Therefore, the rejection is maintained.

Applicant's argument over rejection of claims 1-5, and 7-11 on the ground that the instant application has a priority of 07/31/2002 beat the priority of the '802

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publication as 08/23/2002 is found persuasive. Therefore, the rejection has been withdrawn.

**Obviousness-type double patenting rejection**

Applicant's argument over the ODP rejection has been considered, and is not persuasive, because the pending claims are not allowable. Therefore, the rejection is maintained.

**Claim Objection**

The claim objection is maintained because claims 6 and 12 still depended on the rejected claim.

***Conclusion***

- No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

/Yong Chu/  
Patent Examiner  
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